Remarks

Claims 20, 52 and 65-106 are currently pending.

As requested by the Examiner (*see*, Paper No. 12232005, page 2, part 3) Applicants have herein amended the first paragraph of the specification to update the status of U.S. application 09/848,295 as "U.S. Patent No. 6,623,941".

Rejections under 35 U.S.C. § 112

Claims 20, 52, 65, 66, 68, 69, 71, 72, 74-76, 78, 79, 81, 82, 84-87, 89, 90, 92, 93, 95-98, 100, 101, 103, 104 and 106 have been rejected under 35 U.S.C. § 112, first paragraph. In asserting this rejection, the Examiner alleged "The specification describes a polypeptide having the sequence consisting of SEQ ID NO: 2, with no specific and substantial asserted utility, other than being preferentially expressed in mature B cell." *See*, Paper No. 12232005, page 3, part 4. Applicants respectfully disagree and traverse the rejection on this basis. Among the several specific and substantial utilities asserted by the specification, the specification provides:

> **[0016]** The present invention also provides diagnostic assays such as quantitative and diagnostic assays for detecting levels of TR20 protein. Thus, for instance, a diagnostic assay in accordance with the invention for detecting over-expression of TR20, or soluble form thereof, compared to normal control tissue samples may be used to detect the presence of tumors.

See, specification, page 4, paragraph [0016]. Hence, the specification provides, *inter alia*, that the present invention provides a means to detect the presence of tumors.[1] Applicants submit that such utility would indisputably be found by those of ordinary skill in the art to be both specific and substantial.

In asserting the present rejection the Examiner also alleged:

> However, the claims as written include polypeptides comprising

[1] Applicant need only make one credible assertion of specific utility to satisfy 35 U.S.C. § 112. *See*, M.P.E.P. § 2107.02 (I).

> fragments and homologues, encompass polypeptides that vary in length and also in amino acid composition. The instant disclosure of one polypeptide, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in Regents of the University of California v Eli Lilly & Co..."

See, Paper No. 12232005, page 3, part 4.

Applicants respectfully disagree and traverse the rejection on this basis. As an initial matter, the situation in the present application is quite different from that in Regents of the University of California v Eli Lilly & Co. (119 F.3d 1559 (Fed. Cir. 1997)). In Regents, the patent application at issue disclosed a nucleic acid sequence encoding rat insulin. *See e.g.*, Regents at 1562 and 1566. Therefore, in view of this *single species* disclosure, the claims *drawn to a genus* encompassing nucleic acids encoding *vertebrate, mammalian, and human insulin* (*i.e.*, claims 1, 2, 4, 6 and 7) were rejected by the Federal Circuit as lacking adequate written description under 35 U.S.C. § 112. Regents at 1566-1570. In rendering this decision, the Federal Circuit explained:

> In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," *without more,* is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Regents at 25 (emphasis added). Accordingly, since the patent application in Regents described only a single nucleic acid encoding rat insulin, the Federal Circuit found the application lacking written description adequate for appropriately claiming a genus encompassing *all vertebrate* cDNAs encoding insulin. Regents at 1566-1570.

In the present application, however, the pending claims do not claim a genus beyond the scope of the written description provided by the specification. Indeed, the present claims are drawn to polypeptides (or portions thereof) at least 90% identical to SEQ ID NO:2 or to the polypeptide encoded by the cDNA in ATCC Deposit No. PTA-1997. The fact that the claimed polypeptides may "vary in length and also in amino acid composition" is not a sound legal or policy based rationale for rejecting the currently

pending claims because all of the polypeptides, no matter how varied in length or amino acid composition, are not varied beyond the scope of the polypeptide sequence as disclosed and described in the present specification. Therefore, the present situation is quite unlike the case in Regents where applicants disclosed a *rat* insulin nucleic acid and attempted to claim *all vertebrate* nucleic acids encoding insulin. In the present application, the claims are only drawn to polypeptides at least 90% identical to SEQ ID NO:2 or to the polypeptide encoded by the deposited cDNA as described in the present application. Hence, given the present application, those of ordinary skill the art could readily identify and recognized each species of the claimed embodiments of the present invention. As such, the present application fully describes the entire genus to which the presently pending claims are drawn because the currently pending claims and specification distinguishes the claimed genus from others, specifically defines the polypeptides that fall within the genus, and provides the necessary written description so that one skilled in the art can visualize, recognize, and identify members of the genus.

In like manner, the Examiner asserted the current rejection by alleging:

> A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by amino acid sequence, falling within the scope of the genus, or a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, only one polypeptide, with no disclosed activities...To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present in the claims are a partial structure in the form of a recitation of percent identity, and a requirement that the sequence be naturally occurring. Clearly, such does not constitute disclosure of a representative number of examples of, nor adequate written description for the claimed genus."

See, Paper No. 12232005, pages 4-5, section 4.

Applicants respectfully disagree and traverse the rejection on this basis. In particular, the present specification does, in fact, provide "recitation of structural features common to the genus, which features constitute a substantial portion of the genus." In

this regard, the structural feature which is "**common to the genus**" is provided by SEQ ID NO:2 and by the polypeptide sequence encoded by the deposited cDNA. Furthermore, the "**recitation of structural features**" common to the genus is provided by the description "at least 90%" or "at least 95%" identical to the common sequence. Hence, given that the written description of the claimed polypeptides share a finite level of percent identity in common with a reference sequence, as provided in the present specification, those of ordinary skill in the art can readily recognize and identify each species of polypeptide within the claimed genus. As such, the specification provides sufficient written description to reasonably convey to those of ordinary skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Accordingly, in view of the above explanations, Applicants respectfully request that the rejection of claims 20, 52, 65, 66, 68, 69, 71, 72, 74-76, 78, 79, 81, 82, 84-87, 89, 90, 92, 93, 95-98, 100, 101, 103, 104 and 106 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Claims 52, 75-84 and 96-106 were also rejected under 35 U.S.C. § 112, first paragraph, in reference to Applicants deposit of cDNA clone HPMKI40 with the ATCC as Deposit No. PTA-1997. In particular, the Examiner requested an affidavit or declaration assuring public availability of the deposited material upon allowance of the presently pending claims.

As an initial matter, Applicants note that ATCC Deposit No. PTA-1997 has already been released to the public in view of issuance of U.S. Patent No. 6,623,941 (of which the present application claims benefit). In evidence of the release of ATCC Deposit No. PTA-1997, Applicants enclosed herewith Exhibit 1 (copy of letter authorizing the ATCC to release restrictions on availability of the deposit). Furthermore, in view of the Examiners request with respect to the deposit the applicants agent herein provides the following declaration of assurance:

Availability of the Deposit

> Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit

> was made on June 7, 2000, accepted by the ATCC, tested to assure viability, and given ATCC Accession Number PTA-1997. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number PTA-1997 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b).

Finally, the Examiner also requested that the specification be amended "to recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited [material] is required." *See*, Paper No. 12232005, page 6. Applicants note the specification already contains all of the above requested information at page 7, paragraph [0025]. Accordingly, the request to amend the specification in this regard is unwarranted.

In view of the above amendments and explanations, Applicants respectfully request that all rejections of the currently pending claims be reconsidered and withdrawn.

Conclusion

Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the present application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

If there are any fees, not already accounted for, due in connection with the filing of this paper, please charge such fees to our Deposit Account No. 08-3425.

Date: June 28, 2006

Respectfully submitted,

By _____

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KKHDAS/mr

EXHIBIT 1

Human Genome Sciences, Inc.
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James H. Davis, Ph.D., J.D.
Direct dial: 301-251-6039
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Via First Class Mail

Ms. Tanya Nunnally
Patent Administrator
ATCC Patent Depository
10801 University Boulevard
Manassas, VA 20110-2209

Re: ATCC Deposit No: PTA-1997
U.S. Patent No: 6,623,941 B1
HGS Reference No: PF527N

Dear Ms. Nunnally:

Human Genome Sciences, Inc., has been awarded U.S. Patent No. 6,623,941 B1, with claims making reference to ATCC Deposit No. PTA-1997. Pursuant to 37 C.F.R. § 1.808, please release all restrictions on availability of the referenced material to the public subject to the following.

Please furnish the referenced material only if a request for a sample, during the term of the patent:

(1) Is in writing or other tangible form and is dated;

(2) Contains the name and address of the requesting party and the accession number of the deposit; and

(3) Is communicated in writing by the ATCC to Human Genome Sciences, Inc. along with the date the material was furnished and the name and address of the party to whom the sample was furnished.

If you have any questions or concerns, please contact me.

Sincerely yours,

James H. Davis, Ph.D.
Executive Vice President and General Counsel

Date: Aug 31, 2004

JHD/mr

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